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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/810,956	03/26/2004	John C. Bischof	110.02150101	9825
26813 7590 04/13/2007 MUETING, RAASCH & GEBHARDT, P.A. P.O. BOX 581415 MINNEAPOLIS, MN 55458			EXAMINER TOY, ALEX B	
			ART UNIT 3739	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE			MAIL DATE	DELIVERY MODE
3 MONTHS			04/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/810,956

Applicant(s)

BISCHOF ET AL.

Examiner

Alex B. Toy

Art Unit

3739

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 20 February 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 and 32-52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 35-52 is/are allowed.
- 6) ☒ Claim(s) 1-6 and 32-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 March 2005 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Response to Amendment

This Office Action is in response to applicant's amendment filed on February 20, 2007. All previous prior art rejections are maintained. New grounds of rejection are made with respect to new claims 32-34. New claims 35-52 are allowed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-6, and 32 are rejected under 35 U.S.C. 102(b) as being anticipated by Edwards (U.S. Pat. No. 5,472,441).

Regarding claim 1, Edwards discloses a method of performing a thermal surgical procedure, comprising:

identifying biological material to undergo the thermal surgical procedure

(Abstract);

contacting the biological material with an inflammation inducing composition, wherein inflammation is induced in at least a portion of the identified biological material (Abstract, col. 9, ln. 16-24, and col. 11, ln. 7-9, 43-44); and

adjusting the temperature of the identified biological material, wherein at least a portion of the biological material is destroyed after undergoing the thermal surgical procedure (Abstract).

Regarding claim 3, Edwards further discloses that adjusting the temperature comprises raising the temperature above a physiological temperature of the biological material (Abstract).

Regarding claim 4, Edwards further discloses that the biological material is selected from the group consisting of cells, tissues, and combinations thereof (Abstract).

Regarding claim 5, Edwards further discloses that the cells are tumor cells (Abstract).

Regarding claim 6, Edwards further discloses that the tissues are selected from the group consisting of tumor tissues, liver tissue, prostate tissue, breast tissue, kidney tissue, vascular tissue, gastrointestinal tissue, muscle tissue, skin tissue, connective tissues, and combinations thereof (Abstract).

Regarding claim 32, Edwards further discloses that the composition comprises a compound selected from the group consisting of at least one virus, at least one bacterium, ethanol, cytokines, interleukins, chemokines, oxygen-free radicals, bacterial lipopolysaccharides, and combinations thereof (col. 11, ln. 7-9, 43-44).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 3739

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148

USPQ 459 (1966), that are applied for establishing a background for determining

obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1 and 2 are rejected under 35 U.S.C. 103(a) as being unpatentable over Daniel (U.S. PGPub 2002/0133148 A1) in view of Edwards ('441).

Regarding claim 1, Daniel discloses a method of performing a thermal surgical procedure, comprising:

identifying biological material to undergo the thermal surgical procedure (Abstract and pg. 20, ¶ 209);

contacting the biological material with a chemotherapeutic composition (pg. 8, ¶ 106, pg. 17, ¶ 179, and pg. 19, ¶ 197-198); and

adjusting the temperature of the identified biological material, wherein at least a portion of the biological material is destroyed after undergoing the thermal surgical procedure (pg. 4, ¶ 69).

The claim differs from Daniel in calling for the composition to induce inflammation in at least a portion of the identified biological material. Edwards, however, teaches an analogous device that ablates tumor tissue in combination with delivering a

Art Unit: 3739

chemotherapeutic agent. Edwards further teaches that efficacious chemotherapeutic agents include inflammation inducing compounds (Abstract, col. 9, ln. 16-24, and col. 11, ln. 7-9, 43-44). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have used an inflammation inducing chemotherapeutic composition in the method of Daniel in view of the teaching of Edwards as an obvious type of chemotherapeutic agent that is known in the art to be efficacious in combination with ablation treatment.

Regarding claim 2, Daniel further discloses adjusting the temperature to comprise lowering the temperature below a physiological temperature of the biological material (pg. 4, ¶ 69).

Claim 33 is rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards ('441) in view of Krieg (U.S. PGPub 2003/0050268 A1).

Regarding claim 33, the claims differ from Edwards in calling for the inflammation inducing compound to be TNF-alpha. Krieg, however, teaches that IFN-alpha, IFN-beta, IFN-gamma, TNF-alpha, TNF-beta, and IL-8 are among the principal cytokines involved in inflammation (pg. 48, ¶ 192). Since Edwards already discloses using inflammatory cytokines IFN-alpha, IFN-beta, and IFN-gamma (col. 11, ln. 7-9, 43-44), it would have been obvious to one of ordinary skill in the art and required only routine skill at the time the invention was made to have used TNF-alpha in the method of Edwards in view of the teaching of Krieg as an obvious alternate inflammatory cytokine that is well-known in the art.

Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Edwards ('441).

Regarding claim 34, Edwards discloses delivering saline or a chemotherapeutic fluid containing an inflammation inducing compound (Abstract). Edwards does not disclose what fluid the chemotherapeutic is in, but it would have been obvious to one of ordinary skill in the art and required only routine skill to use saline as the carrier since Edwards already discloses the use of saline and saline is an obvious and well-known carrier in the art.

Response to Arguments

Applicant's arguments with respect to claims 1-6 have been fully considered but they are not persuasive.

Regarding claim 1, applicant argues that Edwards does not inherently disclose contacting the biological material with an inflammation inducing composition, wherein inflammation is induced in at least a portion of the identified biological material.

In response, Edwards clearly discloses contacting tissue with IFN-alpha, IFN-beta, or IFN-gamma (Abstract, col. 9, ln. 16-24, and col. 11, ln. 7-9, 43-44). The examiner maintains that it is scientifically known that IFN-alpha, IFN-beta, and IFN-gamma inherently induce inflammation. For support of this statement see pg. 48, ¶ 192 of Krieg (U.S. Pub. No. 2003/0050268 A1). Applicant should note that Krieg is cited only in support of this scientific knowledge to show inherency. (i.e. The scientific teaching of

Art Unit: 3739

inherent inflammatory properties stands regardless of the invention and intended use of Krieg.)

Regarding applicant's arguments with respect to the rejections of claims 1 and 2 under 103(a) using Daniel in view of Edwards, see the above response.

Allowable Subject Matter

Claims 35-52 are allowed.

The following is a statement of reasons for the indication of allowable subject matter:

Regarding independent claim 35, the prior art does not disclose or suggest contacting biological material with an inflammation inducing composition from about 1 to about 4 hours prior to adjusting the temperature of the biological material as claimed.

Regarding independent claim 44, the prior art does not disclose or suggest contacting biological material with an inflammation inducing composition for an interval of about 4 hours to about 48 hours and then adjusting the temperature of the biological material as claimed.

Art Unit: 3739

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alex B. Toy whose telephone number is (571) 272-1953. The examiner can normally be reached on Monday through Friday, 8:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3739

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AT *AT*
4/11/07

Michael Reffley
MICHAEL REFFLEY
PRIMARY EXAMINER